

## REMARKS

In an Office Action mailed June 3, 2005, the Examiner finally rejected Claims 1-5 and 11-15. All claims were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,655,387 to Mathieu et al.

The Applicants respond to the Examiner's rejections below. In view of the amendments noted above and the arguments presented herein, the Applicants respectfully request reconsideration of the merits of this application.

### Rejections Under § 102(b)

The Examiner rejected Claims 1-5 and 11-15, alleging that Mathieu et al. inherently anticipates the methods described in the above-identified application. Specifically, the Examiner alleged that Mathieu et al. discloses patentably indistinct methods of orally administering Vitamin D analogues to delay the onset of Type 1 diabetes or reduce the severity of diabetes symptoms. The Applicants respectfully disagree.

Although the Examiner has given little weight to the Declaration submitted in the previous Response, Applicants wish to reiterate that a reference cited against an application under §102 cannot inherently anticipate a claim unless that reference is enabling. See Smithkline Beecham Corp. v. Apotex Corp., 247 F.Supp.2d 1011 (N.D.Ill. 2003) (vacated on other grounds by 403 F.3d 1328 (Fed. Cir. 2005)). Likewise, for a claim to be anticipated under inherency, the "inherent" element must be necessarily present in the reference – it is not sufficient for a reference to suggest methods that may or may not be successfully used to produce a new invention. See Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research, 346 F.3d 1051, 1052 (Fed. Cir. 2003); see also In re Cruciferous Sprout Litigation, 301 F.3d 1343, 1352 (Fed. Cir. 2002).

Mathieu et al. does not enable a skilled artisan to reduce the risk of Type I diabetes in a predisposed human patient by up to 90% via oral administration of Vitamin D analogs. For one, Mathieu et al. made a mere passing reference to oral administration. See column 4, lines 45-64. In fact, no oral administration was even demonstrated in Mathieu et al. – each Example was to injection of Vitamin D analogs. Additionally, the Declaration by Julia Zella demonstrated that the methods of injection disclosed in Mathieu et al. failed in "reducing the risk of type I diabetes in a predisposed human patient by up to 90%." As such, if Mathieu et al. was not enabling for injection of Vitamin D analogs, it certainly cannot be enabling for oral administration of Vitamin D analogs – even to a skilled artisan. Therefore, Applicants

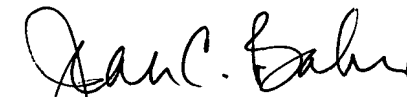
again respectfully request reconsideration of the rejection as applied to Claims 1 and 11, and as applied to Claims 2-5 and 12-15, which depend therefrom.

Fees

A three-month extension of time is believed due with this Response. Please consider this to be a petition for the appropriate extension of time and a request to charge the petition fee Deposit Account No. 17-0055. Applicants also file an RCE and have scheduled an in-person interview with Examiner Sharareh on December 15, 2005. No additional fee is believed due in connection with this submission. However, if a fee is due, in this or any subsequent response, please charge the fee to Deposit Account No. 17-0055.

Respectfully submitted,

Hector F. DeLuca, et al.

A handwritten signature in cursive script, appearing to read "Jean C. Baker", is written over a horizontal line.

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